satisfaction of inpatient and outpatient setting are influenced by the different variables. The disease cure is enough to interpreter the whole satisfaction in inpatient. But in outpatient setting, other than the variable of symptoms relieved, there are more variables influenced the patient satisfaction. However, the other medical process such as waiting time for several stages, patient privacy, patient right, informed consent and so on did not influence patient satisfaction.

**PMC48**

## UPDATE OF TRENDS IN THE INCLUSION OF PATIENT-REPORTED OUTCOME (PRO) DATA IN APPROVED DRUGS LABELING BY FDA AND EMEA

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**OBJECTIVES:** The PROLabels database (www.mapi-prolabels.org) was developed to provide easy access to Patient-Reported Outcomes (PROs) included in approved labeling of products in Europe and the USA. Two years after its launch, the coverage of FDA labels has been extended to give a more comprehensive image of the current use of PROs in clinical studies. **METHODS:** In 2006, the database opened with drugs approved in Europe through the centralized procedure established by the EMEA in January 1995 and with New Molecular Entities (NME) approved in the USA since January 1998. The extension project focused on other chemical types approved by FDA (e.g. New dosage form, New combination, etc.) and on NME approved before 1998. Once a PRO claim was identified in a label, the drug was added in PROLabels and the following information was retrieved: the PRO claim, description of clinical studies supporting the claim, description of PRO endpoints and measures used, pharmacological action of products and information source. **RESULTS:** Updated figures resulting from this major extension of PROLabels will be presented. These new figures will include the number of drug products present in the database with the FDA/EMEA distribution, the most represented therapeutic areas (currently nervous system diseases: 27.8%, immune system diseases: 20.6%, respiratory tract diseases: 16.5%, pathological conditions, signs and symptoms: 14.9%, and mental disorders: 14.6%), and the most frequently measured PROs (currently Signs and Symptoms followed by Health-Related Quality of Life (HRQL)). Finally, any change in the rate of PRO data found overall in FDA approvals will be checked. **CONCLUSIONS:** This extension of the FDA coverage of the PROLabels database allows a clearer picture of the use of PROs to assess patients' treatment benefit to be drawn. In addition, it facilitates the examination of the discrepancies between the US and European regulatory agencies.

**PMC49**

## COMPARISON OF HEALTH LOCUS OF CONTROL BETWEEN PHYSICIANS AND THE GENERAL PUBLIC: MULTI-GROUP STRUCTURAL EQUATION MODELING

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**OBJECTIVES:** Health locus of control (HLC) is associated with health-related behaviors such as adherence and participation in health screening. However, HLC among physicians may be different from that among the general public. It is important to understand the potential gap in HLC between physicians and the general public. The aim of the study included two steps: 1) to evaluate item bias of the HLC scale between physicians and the general public, and 2) to characterize HLC among physicians compared to the general public. **METHODS:** Data for the general public were obtained from the health diary study that involved a random sample from a nationally representative group of households in Japan. Physicians' data were collected from a web-based survey of Japanese physicians. Multi-group structural equation modeling was used for examining item bias in the Japanese version of the HLC scale (HLCS-J) between the two groups. Differential item functioning (DIF), including uniform and non-uniform types, were used for measuring item bias. Dimensions with no uniform and non-uniform DIFs were then compared using multiple linear regressions. **RESULTS:** Data on the HLCS-J of 2194 people from the general public and 895 physicians were available. Uniform DIF was recognized for the dimensions of internal, professional control and control by spiritual powers. Chance and family control dimensions had no DIF. Mean score for chance control (17.2) among physicians was greater than that (14.9) among the general public (adjusted $p < 0.001$), while mean score for family control (21.7) among physicians was lower than that (22.1) among the general public (adjusted $p < 0.001$). **CONCLUSIONS:** Our psychometric evaluation of the HLCS-J indicates item bias in the dimensions of internal, professional control and control by spiritual powers. Physicians believe that chance has a greater impact but family control has a lesser impact on health than do members of the general public.

**PMC50**

## THE SUITABILITY OF VISUAL ANALOGUE SCALES (VAS) FOR COLLECTING PATIENT-REPORTED OUTCOMES (PRO) DATA FROM INTERNATIONAL SETTINGS

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**OBJECTIVES:** The VAS is a common response scale in PRO questionnaires, which are used in multinational studies from which data is pooled. This study was designed to evaluate the suitability of VAS for use in different international settings, specifically to evaluate the cognitive processes and challenges occurring when respondents from a range of countries/cultures complete VAS. **METHODS:** Adults were recruited from: UK; Mexico; Spain; Malaysia; India; South Africa, with approximately 50:50 males/females and higher/lower education split. Each completed four VAS followed by a cognitive debriefing interview, once before and once after receiving standardized instructions. RESULTS: Thirty-seven lay persons were interviewed across 6 countries, mean age was 46 ± 19; 51.4% were male. Several respondents commented on the unfamiliar style of the VAS. Some reported the anchors as inappropriate/ambiguous, impeding scale completion, or that anchor wording caused them to avoid scale extremities. Respondents noted the lack of intermediate markers on the VAS, therefore having to rely on 'guesswork': most used quantitative rather than qualitative strategies when deciding where to place their mark. Some had concerns that 'guesswork' led to inaccurate responses. British and Spanish respondents used principally quantitative methods whereas Zulu speakers relied more on qualitative techniques. Respondents from Malaysia, South Africa and India were more inclined to report challenges; Zulu and Tamil speakers completed the VAS in the least conventional way. **CONCLUSIONS:** The study provides substantial evidence that the use of VAS in different international